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December 28, 2022

**VIA ECF**

The Honorable Lorna G. Schofield  
United States District Court  
Southern District of New York  
500 Pearl Street  
New York, NY 10007

Re: Portal Instruments, Inc. v. LEO Pharma A/S, Case No. 1:22-cv-09156-LGS

Dear Judge Schofield:

The parties respectfully submit this joint letter pursuant to the Court's November 16, 2022 Order in the above-captioned action (Dkt. 10). As directed, the parties also attach a Proposed Civil Case Management Plan and Scheduling Order.

**1. Statement of the Case**

Plaintiff's Statement: Plaintiff Portal Instruments, Inc. ("Plaintiff" or "Portal") commenced this action to recover several million dollars owed to it by Defendant LEO Pharma A/S ("LEO"). Pursuant to the parties' Collaboration and License Agreement (the "Agreement") LEO had to make a series of quarterly payments ("Development Payments") to Portal in return for Portal's development of a drug delivery system for LEO. LEO also had to make one-time payments in response to certain triggering events ("Milestone Payments"). LEO had the right to terminate the entire Agreement, or the development of any system under the Agreement, but only upon 90 days' written notice.

LEO made quarterly Development Payments without incident through the third quarter of 2021. On September 15, 2021, LEO sent Portal a notice purporting to terminate the development of the drug delivery system, effective December 22, 2021. But LEO refused to make the quarterly Development Payment for the fourth quarter of 2021, which was due on October 1, 2021, and which covered the 90-day notice period, during which the Agreement remained in effect.

In February 2021, before the Agreement was terminated, a \$1 million Milestone Payment became due and owing to Portal from LEO. This payment was triggered when Charles River Laboratories completed an animal trial of Portal's system (the "PK Study"), and confirmed that Portal's system successfully passed the PK Study. Before LEO terminated the agreement, it

admitted that Portal's product had passed the PK Study. However, likely in conjunction with its decision to terminate the Agreement, LEO decided not to make the Milestone Payment and undertook a post-hoc review of the data from the PK Study – a review not contemplated by the Agreement – in a bad faith attempt to justify its non-payment.

Portal's Complaint asserts claims for breach of contract and breach of the implied covenant of good faith and fair dealing, based on LEO's failure to make the required Development Payment and Milestone Payment, and its extra-contractual post-hoc analysis of the PK Study. The major legal and factual issues in this case are 1) whether LEO was obligated to make the \$1.5 million Development Payment for the 90-day period following LEO's notice of intent to terminate the project, 2) whether LEO was obligated to make the \$1 million Milestone Payment associated with the PK Study triggering event, and 3) whether LEO's actions with respect to the development payment and the PK Study constituted bad faith.

Defendant's Statement: On December 3, 2019, the parties entered into a Collaboration and License Agreement ("Agreement"), under which LEO elected to use Portal's services to develop a needle-free drug delivery system. In this action, Portal seeks to recover for LEO's purported breaches of the Development Fee and Milestone Payment provisions of the Agreement, but its claims are barred by the plain language of the contract.

*Development Fee Claim.* In exchange for Portal's assistance in developing the drug delivery system, LEO agreed to make installment payments towards a Development Fee until it elected to cease development or made 10 such payments, whichever occurred first. The Agreement provided that, if LEO elected to cease development, LEO would have "no obligation to make any future installment payments towards the ... Development Fee." Agreement § 7.2(a). The Complaint concedes that on September 15, 2021, LEO elected to cease development of the drug delivery system. Compl. ¶ 21. As a result of that election, LEO had "no obligation to make any future installment payments" under the plain terms of the Agreement.

Portal attempts to obfuscate the issue by arguing that LEO's ultimate termination of the Agreement was not effective until after 90 days, but this confuses an election to seek development (which was effective immediately and required no advance notice) with termination of the contract. The parties agreed that, following an election to cease development, LEO would have no obligation to make any future installment payments. Because it is undisputed that LEO elected to cease development on September 15, 2022, LEO had no further obligation to make any future Development Fee payments, including the October 1, 2021 payment which Portal seeks to recover, irrespective of the effective date of contract termination.

*Milestone Payment Claim.* LEO also agreed to make Milestone Payments upon satisfaction of certain Milestone Events defined in the Agreement. The Agreement provided that one such Milestone Payment would be due upon "[c]ompletion of a pharmacokinetic study in animals in which a Third Party determines that delivery of LEO Pharma's Drug via the Device is *bioequivalent to delivery via a needle/syringe*," which "shall include a statement that the *bioequivalence criteria have been met* ...." Agreement § 7.3 (emphasis added).

On June 15, 2021, Charles River Laboratories signed a Pharmacokinetic Report (the “PK Study Report”), which described a study involving the drug delivery system. The PK Study Report did not determine bioequivalence, nor did it “include a statement that the bioequivalence criteria have been met” as required to trigger the relevant Milestone Payment. Indeed, Portal does not even allege that the study included the required finding, but asserts instead that it contained a “surrogate” finding of bioequivalence—a concept found nowhere in the Agreement. *See* Compl. ¶ 50. As a result, the Milestone Event was never reached, and Portal’s Milestone Payment claim must be dismissed.

*Good Faith and Fair Dealing Claim.* Finally, the Complaint asserts that LEO breached the implied covenant of good faith and fair dealing by not making the Development Fee payment and Milestone Payment. The claim fails for the same reasons explained above, as well as the long-established principle that the covenant of good faith and fair dealing cannot be used to vary the express terms of an agreement.

For the reasons explained above, this case can be resolved on a motion to dismiss based on allegations of the Complaint and documents referenced therein. To the extent any further development of the record is necessary, the major legal and factual issues that are most important to resolving this case are: (1) whether LEO had an obligation to make a Development Fee payment after it elected to cease development, (2) whether the PK Study Report triggered a Milestone Payment, and (3) whether Portal can maintain a claim for breach of the implied covenant of good faith and fair dealing based on the same conduct underlying its breach of contract claims.

## **2. Basis of Subject Matter Jurisdiction and Venue**

This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(2) because there is complete diversity of citizenship among the parties and the matter in controversy exceeds the sum or value of \$75,000. Portal is a Delaware corporation with a principal place of business in Cambridge, Massachusetts. LEO is a Danish corporation with its principal place of business in Ballerup, Denmark. It is undisputed that the sums in dispute exceed the \$75,000 requirement under Section 1332(a).

## **3. Anticipated Motions**

Plaintiff’s Statement: Portal anticipates filing a Motion for Judgment on the Pleadings, and if necessary, a Motion for Summary Judgment.

Defendant’s Statement: As explained in detail in LEO’s pre-motion letter dated December 5, 2022 (ECF No. 19), LEO anticipates filing a motion to dismiss. To the extent that LEO’s anticipated motion to dismiss is denied, in whole or in part, LEO anticipates filing a motion for summary judgment on any remaining claims.

## **4. Status of Discovery**

No discovery has yet occurred in this case.

Plaintiff's Statement: Plaintiff anticipates seeking discovery on, among other topics, 1) LEO's design of the study performed by CRL, 2) LEO's post-hoc analysis of study data from the CRL study, and 3) any defenses asserted by LEO.

Defendant's Statement: To the extent any discovery is required, Defendant anticipates seeking discovery on, among other topics, (1) the PK Study Report and related matters, and (2) Portal's claims and allegations.

## **5. Computation of Damages**

Plaintiff's Statement: Portal seeks damages in the amount of \$1.5 million for LEO's failure to make the October 1, 2021 Development Payment and \$1 million for LEO's failure to make the Milestone Payment, plus attorneys' fees, costs and pre-judgment interest.

Defendant's Statement: LEO disputes that Portal is entitled to any damages, attorneys' fees, costs, or interest, and reserves the right to seek its own attorneys' fees.

## **6. Status of Settlement Discussions**

Plaintiff's Statement: The parties had several discussions attempting to reach resolution since October 2021, but have been unable to reach an agreement.

Defendant's Statement: The parties had several discussions regarding settlement prior to Portal initiating this action. The parties continued settlement discussions after LEO filed its pre-motion letter regarding its anticipated motion to dismiss, and those discussion are ongoing.

**LATHAM & WATKINS** LLP

Respectfully submitted,

**LATHAM & WATKINS LLP**

/s/ Steven J. Pacini

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

Portal Instruments, Inc.,

Plaintiff,

v.

LEO Pharma A/S,

Defendant.

Case No. 1:22-cv-09156-LGS

CIVIL CASE MANAGEMENT PLAN AND  
SCHEDULING ORDER

LORNA G. SCHOFIELD, United States District Judge:

This Civil Case Management Plan is submitted by the parties in accordance with Fed. R. Civ. P. 26(f)(3).

1. All parties [consent    / do not consent X] to conducting all further proceedings before a United States Magistrate Judge, including motions and trial. *See* 28 U.S.C. § 636(c). The parties are free to withhold consent without adverse substantive consequences. *[If all parties consent, the remaining paragraphs need not be completed.]*
2. The parties [have X / have not       ] conferred pursuant to Fed. R. Civ. P. 26(f).
3. This case is governed by one of the following sets of rules, and the parties' proposed dates in this order have been adjusted accordingly.
  - a. An employment case governed by the Initial Discovery Protocols for Employment cases? <https://nysd.uscourts.gov/hon-lorna-g-schofield>.  
[Yes        / No X]
  - b. A case governed by Local Civil Rule 83.10, Plan for Certain § 1983 Cases Against the City of New York? <https://nysd.uscourts.gov/rules>.  
[Yes        / No X]
  - c. A patent case subject to the Local Patent Rules and the Court's Individual Rules? <https://nysd.uscourts.gov/rules> and <https://nysd.uscourts.gov/hon-lorna-g-schofield>  
[Yes        / No X]
  - d. A wage and hour case governed by Initial Discovery Protocols for Fair Labor Standards Act? <https://nysd.uscourts.gov/hon-lorna-g-schofield>.

[Yes \_\_\_\_\_ / No X]

## 4. Alternative Dispute Resolution/Settlement

- a. Settlement discussions [have X / have not \_\_\_\_\_] taken place.
- b. Counsel for the parties have discussed an informal exchange of information in aid of early settlement and have agreed to exchange the following:

N/A

- c. Counsel for the parties have discussed the use of the following alternate dispute resolution mechanisms for use in this case: (i) a settlement conference before a Magistrate Judge; (ii) participation in the District's Mediation Program; and (iii) retention of a private mediator. Counsel for the parties propose the following alternate dispute resolution mechanism for this case:

Prior to the filing of litigation the parties discussed settlement and were unable to reach agreement. Subsequent to the filing of litigation, the parties once again discussed settlement, and those discussions are ongoing. In light the parties' ongoing discussions, they do not believe that an alternative dispute resolution mechanism would be beneficial at this time.

- d. Counsel for the parties recommend that the alternate dispute resolution mechanism designated in paragraph 4(c) be employed at the following point in the case (*e.g.*, within the next 60 days; after the deposition of plaintiff is completed (specify date); after the close of fact discovery):

After decision on LEO's anticipated motion to dismiss and any fact discovery is complete.

- e. The use of any alternative dispute resolution mechanism does not stay or modify any date in this Order.

5. No additional parties may be joined after December 28, 2022 without leave of Court.

6. Amended pleadings may be filed without leave of Court until December 28, 2022.

7. Initial disclosures pursuant to Fed. R. Civ. P. 26(a)(1) shall be completed no later than December 28, 2022.

## 8. Fact Discovery

All fact discovery shall be completed no later than: May 4, 2023

- a. Requests for production of documents pursuant to Fed. R. Civ. P. 34 shall be served by: January 11, 2023.
- b. Parties will promptly begin production of responsive documents upon receipt of the other side's requests for production, substantially complete production by March 3, 2023, and complete productions in response to all document requests by March 27, 2023. Do the parties anticipate e-discovery? [Yes X / No   ]
- c. Interrogatories pursuant to Fed. R. Civ. P. 33 shall be served by: March 27, 2023
- d. Depositions pursuant to Fed. R. Civ. P. 30, 31 shall be completed by May 4, 2023
- e. Requests to admit pursuant to Fed. R. Civ. P. 36 shall be served by March 27, 2023
- f. Any of the deadlines in paragraphs 8(b) through 8(f) may be extended by the written consent of all parties without application to the Court, provided that all fact discovery is completed by the date set forth in paragraph 8(a).

## 9. Expert Discovery [if applicable]

- a. Anticipated types of experts if any:

Should this action survive Defendant's anticipated motion to dismiss, Defendant believes that it may be necessary to obtain expert testimony relating to the PK Study Report and/or bioequivalence.

- b. If you have identified types of experts in question 9(a), all expert discovery shall be completed no later than June 19, 2023.  
*[Within 45 days from the date in paragraph 8(a), i.e., the completion of all fact discovery, absent exceptional circumstances.]*
- c. If you have identified types of experts in question 9(a), by April 4, 2023 the parties shall meet and confer on a schedule for expert disclosures, including reports, production of underlying documents and depositions, provided that (i) expert report(s) of the party with the burden of proof shall be due before those of the opposing party's expert(s); and (ii) all expert discovery shall be completed by the date set forth in paragraph 9(b).

10. This case [is X / is not   ] to be tried to a jury.

11. Counsel for the parties have conferred and their present best estimate of the length of trial is 2 days.
12. Other issues to be addressed at the Initial Pretrial Conference, including those set forth in Fed. R. Civ. P. 26(f)(3), are set forth below:

The parties have agreed to this schedule, which conforms to the Court's guidance that discovery should ordinarily be completed within 120 days, on the assumption that document production will be limited in scope and that the need for translation of foreign-language documents will not significantly delay document collection and review. In the event that these assumptions prove incorrect, the parties acknowledge that it may be necessary to apply to the Court for a brief extension of the discovery schedule. Each party reserves its rights to make or oppose any such application.

13. Status Letters and Conferences

- a. By March 6, 2023 [*60 days after the commencement of fact discovery*], the parties shall submit a joint status letter, as outlined in Individual Rule IV.A.2.
- b. By May 18, 2023 [*14 days after the close of fact discovery*], the parties shall submit a joint status letter, as outlined in Individual Rule IV.A.2 and, in the event that they have not already been referred for settlement discussions, shall also advise the Court whether or not they request a referral for settlement discussions as provided in Paragraph 4(c) above.
- c. On July 3, 2023 at 10 A.M. [*usually 14 days after the close of all discovery*], a pre-motion conference will be held for any anticipated dispositive motions, provided:
  - i. A party wishing to file a summary judgment or other dispositive motion shall file a pre-motion letter **at least two weeks before the** conference and in the form provided in the Court's Individual Rule III.A.1. Any party wishing to oppose shall file a responsive letter as provided in the same Individual Rule. The motion will be discussed at the conference. To join the conference, the parties shall call (888) 363-4749 and use Access Code 558-3333. The time of the conference is approximate, but the parties shall be ready to proceed at that time.
  - ii. **If no pre-motion letter is timely filed, this conference will be canceled and the matter placed on the Court's trial-ready calendar.** The parties will be notified of the assigned trial-ready date and the filing deadlines for pretrial submissions. The parties are warned that any settlement discussions will not stay pretrial deadlines or the trial date.

**LATHAM & WATKINS** LLP

This Order may not be modified or the dates herein extended, except as provided in paragraph 8(g) or by further Order of this Court for good cause shown. Any application to modify or extend the dates herein, except as provided in paragraph 8(g), shall be made in a written application in accordance with the Court's Individual Rules and shall be made no less than 2 business days prior to the expiration of the date sought to be extended.

Notwithstanding any other rules governing discovery or other deadlines, the parties shall follow the deadlines set forth herein unless expressly ordered otherwise by the Court.

The Clerk of Court is directed to enter the dates under paragraphs 5, 6, 8(a), 9(b)-(c) and 13(a)-(c) into the Court's calendar.

SO ORDERED.

Dated: \_\_\_\_\_  
New York, New York

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LORNA G. SCHOFIELD  
United States District Judge

Counsel for the Parties:

**LATHAM & WATKINS LLP**

/s/ Steven J. Pacini

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